K090218
Page 1 of 2

510(K) Summary of Safety and Effectiveness

As required by 807.92

APR 15 2009

1. **DEVICE ESTABLISHMENT AND CONTACT PERSON**

Mr. Shuichi Kino
Manager
NEC Display Solutions Ltd.
4-13-23 Shibaura, Minato-ku, Tokyo, 108-0023 Japan
Ph: +81-465-85-2376
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2. **COMPANY REISTRATION NUMBER**

3003623028

3. **DATE SUMMARY PREPARED**

15 December 2008

4. **DEVICE NAME**

Trade Name:	MD213 MC 21.3" Diagnostic Imaging LCD monitor
Model Name:	L218TJ
Common Name:	Color LCD Monitor, Color Diagnostic Display, etc.
Classification Name:	System, Image Processing, Radiological (CLASS II CFR 892.2050)

4. **PREDICATE DEVICE**

MDC2130-2HC 21.3" 2MP Color LCD Monitor by CHILIN Technology Co., Ltd. (K063579).

5. **DEVICE DESCRIPTION**

Medical Display, L218TJ is a 21.3" Color LCD monitor that displays image for medical use. It provides 3 mega pixel (2048*1536) resolution with adjustable gamma gray scale for more precise diagnose use in CT, MRI, HIS, and PACS.

6. DEVICE OF INTENDRD USE

The L218TJ color display is intended to be used for displaying and viewing of digital image diagnosis by trained physicians.

To guarantee the display performance as specified, it must only be used for in conjunction with NEC approved display cards.

The L218TJ cannot be used for a life-support system.

This device must not be used in digital mammography.

This unit is designed for exclusive interconnection with IEC60601-1 certified equipment.

7. CONCLUSION

These two devices have the same target population of trained practitioner in hospital; it shares the same design, same performance and is the same in radiation safety (EN60601-1-2), mechanical safety, electrical safety (UL60601-1) and human factors. It use similar material, and have same compatibility with environment and other device. Comparison table of the principal characteristics of two devices is shown in the Section 3, table 3.3. These two devices also have the same intended use; Therefore we concluded that it is substantially equivalent to MDC2130-2HC by Chi Lin Technology Co., Ltd. (K063579).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NEC Display Solutions, Ltd.
c/o Mr. Morten Simon Christensen
Assistant Manager, Program Reviewer
UL Health Sciences
Underwriters Laboratories, Inc.
455 E. Trimble Road
SAN JOSE CA 95131-1230

APR 15 2009

Re: K090218
Trade/Device Name: Medical Display, L218TJ
Regulation Number: 21 CFR §892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: March 26, 2009
Received: April 1, 2009

Dear Mr. Christensen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

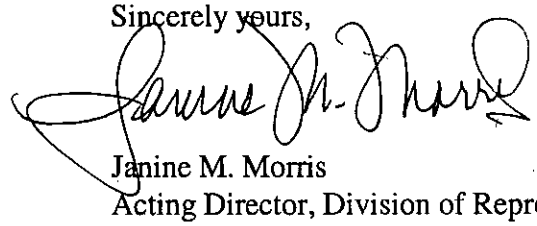
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	(240) 276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	(240) 276-0115
21 CFR 892.xxx	(Radiology)	(240) 276-0120
Other		(240) 276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K090218

Indications for Use

510(k) Number (if known): K090218

Device Name: Medical Display, L218TJ

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This device must not be used in digital mammography.

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Prescription Use ___V___ **AND/OR** **Over-The-Counter Use** _____
(Part 21 CFR 801 Subpart D) **(21 CFR 801 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K090218

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